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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
09/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	09/965,610	CANTOR ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16-18,28-31,35-37 and 39-93* is/are pending in the application.

4a) Of the above claim(s) *48-51 and 55-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16-18,28-31,35-37,39-47 and 52-54, 92, 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE and amendment, both filed 07/16/2009.

Claims 1-9, 16-18, 28-31, 35-37 and 39-91 previously presented.

Claims 92 and 93 currently added.

Claims 1-9, 16-18, 28-31, 35-37 and 39-93 are pending.

Claims 48-51, 55-91 are withdrawn from further consideration.

Claims 1-9, 16-18, 28-31, 35-37, 39-47, 52-54 and 92-93 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the

appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 07/16/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 35, 39-42, 52, 53, 92-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al. (US 5,474,783, provided in IDS filed 09/26/2001).

The present independent claims 1, 35 and 92 are directed to a transdermal drug delivery composition comprising: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; wherein the composition is free of undissolved fentanyl.

Miranda disclosed transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel

adhesive properties (abstract). The drug can be loaded in the dermal formulation from 0.3-50% (col.8, line 65-col.9, line 8). The dermal formulation comprises up to 96% polyacrylate copolymers (col.4, lines 6-12). The polyacrylate copolymer comprises alkyl acrylate monomer including isooctyl acrylate copolymerized with monomer having functional groups including hydroxyethyl acrylate (col.9, lines 21-59). One of the preferred drug to be delivered by this transdermal device is fentanyl as evident by claim 27 of the reference. The reference does not teach undissolved drug in the system, i.e. free from undissolved fentanyl. The reference disclosed transdermal device comprising backing layer and release liner (figure 1). The dermal formulation comprises permeation enhancer in a concentration up to 20% and includes isopropyl myristate, and glycols (col.13, lines 5-24; col.14, lines 5-10).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-9, 16-18, 28-31, 35-37, 39-47, 52-54 and 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al. (US 5,474,783, provided in IDS filed 09/26/2001) in view of Garbe et al. (WO 96/08229, provided in IDS filed 08/27/2002).

Applicant Claims

The present independent claims are directed to a transdermal drug delivery composition comprising: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and (ii) one or more ethylenically unsaturated B monomers copolymerizable with

the A monomer; and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; wherein the composition is free of undissolved fentanyl.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Miranda teaches transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel adhesive properties (abstract). The drug can be loaded in the dermal formulation from 0.3-50% (col.8, line 65-col.9, line 8). The dermal formulation comprises up to 96% polyacrylate copolymers (col.4, lines 6-12). The polyacrylate copolymer comprises alkyl acrylate monomer including isooctyl acrylate copolymerized with monomer having functional groups including hydroxyethyl acrylate (col.9, lines 21-59). One of the preferred drug to be delivered by this transdermal device is fentanyl as evident by claim 27 of the reference. The reference does not teach undissolved drug in the system, i.e. free from undissolved fentanyl. The reference disclosed transdermal device comprising backing layer and release liner (figure 1). The dermal formulation comprises permeation enhancer in a concentration up to 20% and includes isopropyl myristate, and glycols (col.13, lines 5-24; col.14, lines 5-10).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Miranda teaches copolymers of functional and non-functional monomers to form the polyacrylate of the dermal formulation, however, the reference does not exemplify the copolymer. Miranda further does not teach macromonomer as claimed by claims 7-9, or ratios of monomers and macromonomers in the copolymer as claimed by claims 6, 17, 18, 36, and 37. Miranda does not teach the specific enhancers as claimed by claims 43-47.

The missing elements from Miranda were all taught by Garbe.

Garbe teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (page 2, lines 5-23). The copolymer comprises 40-90% of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group and up to 60% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomers. The composition further comprises more than 30% of a macromonomer copolymerizable with the A and B monomers (page 2, lines 5-23). The A monomers are taught on page 4, lines 3-14 with isooctyl acrylate preferred. The B monomers are taught on page 4, line 15 through page 5, line 12, with hydroxyethyl acrylate preferred. The macromonomers are taught on page 5, line 13 through page 8, line 28. Polymethylmethacrylate macromonomers are preferred (page 6, lines 17-18). Example of page 19 teaches copolymer comprising 55% isooctyl acrylate, 40% hydroxyethyl acrylate and 5% polymethylmethacrylate, as claimed by applicants. The softeners of the delivery device affect skin penetration rate and include fatty acids, fatty

acid esters such as methyl laurate and tetraglycols (page 8, line 29 - page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (page 10, lines 7-15). Garbe further contemplates various drugs for delivery by the device including analgesics such as fentanyl (page 12, line 28). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (page 13, line 18-20). The transdermal device comprising the pressure sensitive adhesive taught by Garbe allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with skin, and can be removed cleanly from the skin (page 3, lines 11-15).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal composition to deliver fentanyl wherein the composition comprises a copolymer comprising monomers selected from the group consisting of alkyl acrylates and alkyl methacrylates; and unsaturated monomers; and about 0.3% to about 50% by weight fentanyl; wherein the composition is free of undissolved fentanyl and further comprising permeation enhancer as taught by Miranda, and further select copolymer having 55% isooctyl acrylate, 40% hydroxyethyl acrylate and 5% polymethylmethacrylate as taught by Garbe, and replace the permeation enhancer with enhancer selected from tetraglycol and methyl laurate as taught by

Garbe. One would have been motivated to do so because Garbe teaches that transdermal device comprising such copolymer made of functional and non-functional monomers and macromonomers in specific ratios, and further comprises permeation enhancer allows dissolution of drug and provides matrix that is substantially free of solid undissolved drug, and further the copolymer maintains contact with skin, and can be removed cleanly from the skin. One would reasonably expect formulating transdermal composition to deliver fentanyl comprising copolymer comprising 55% isooctyl acrylate, 40% hydroxyethyl acrylate, 5% polymethylmethacrylate and the composition further containing enhancer selected from tetraglycol and methyl laurate wherein the composition allows dissolution of fentanyl and is free of undissolved fentanyl, and meanwhile the composition has good skin contact adhesion and cleanly removed from the skin.

Regarding the claimed dosage in mg/day and serum concentration of fentanyl as claimed by claims 30, 31, 37, such values are expected to be the same as taught by the prior art since the prior art teaches the same copolymer formulation comprising the overlapping ratios of the same monomers and comprising the same concentration of fentanyl. Therefore, the corresponding dosage in mg/day and plasma concentration expected to overlap with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

8. Applicant's arguments with respect to claims 1-9, 16-18, 28-31, 35-37, 39-47, 52-54 and 92-93 have been considered but are moot in view of the new ground(s) of rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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